UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

OFFICE OF CHEMICAL
SAFETY AND POLLUTION
PREVENTION

OCT 0 3 2017

MEMORANDUM

SUBJECT: *Aureobasidium pullulans* strain DSM 14940 and *Aureobasidium pullulans* strain DSM 14941.

TO: Nicola Steinmetz, Regulatory Action Leader
Microbial Pesticides Branch,
Biopesticides and Pollution Prevention Division (7511P)

FROM: Joel V. Gagliardi, Ph.D., Microbial Ecologist
Microbial Pesticides Branch,
Biopesticides and Pollution Prevention Division (7511P)

THROUGH: John L. Kough, Ph.D., Senior Scientist
Microbial Pesticides Branch,
Biopesticides and Pollution Prevention Division (7511P)

ACTION REQUESTED: Review submitted studies for extended label shelf life on two end-use products.

CONCLUSION:
Product Identity and Characterization – **ACCEPTABLE -** Botector and Blossom Protect are considered stable formulations for up to 30 months at 8°C and for 18 months at 20°C.

DATA REVIEW RECORD:

Active Ingredients:	*Aureobasidium pullulans* strain DSM 14940; *Aureobasidium pullulans* strain DSM 14941.
Product Names:	Botector; Blossom Protect.
Company Name:	BIO-FERM GMBH.
EPA Reg. Nos.:	86174-3; 86174-4.
Chemical Numbers:	046010; 036010.
Decision Numbers:	531807; 531802.
DP Barcodes:	441988; 441972.
MRID Nos.:	503328-01; 503328-02.

NOTES:
Previous reviews are:
Barsoum, I.S. to S. Cerrelli through J.L. Kough. April 16, 2015. Review of an amendment to extend the storage stability of two registered EPs Botector (EPA Reg. No. 86174-3) and Blossom Protect (EPA Reg. No. 86174-4) containing two registered TGAIs: *Aureobasidium pullulans* DSM 14940 & *Aureobasidium pullulans* DSM 14941.

Barsoum, I.S. to S. Cerrelli through J.L. Kough. October 26, 2015. Review of the Registrant's response to a 75-day deficiency letter concerning a petition by the registrant to add Post Harvest use to its registered product Botector containing *Aureobasidium pullulans* DSM 14940 & DSM 14941.

SUMMARY OF REVIEWED DATA:
STUDY TYPES: Physical and Chemical Characteristics.
OCSPP Guidelines: 830.6317.
TEST MATERIALS: Botector and Blossom Protect containing *Aureobasidium pullulans* strain DSM 14940 and *Aureobasidium pullulans* strain DSM 14941.
MRID No.: 503328-01; 503328-02.
DISCUSSION: The registrant submitted studies on only one of the end-use products with the rationale that Botector contains only active ingredients (50% by weight each of *Aureobasidium pullulans* strain DSM 14940 and *Aureobasidium pullulans* strain DSM 14941) and Blossom Protect is the same formulation with a single inert ingredient at 35.5% (32.25% by weight each of *Aureobasidium pullulans* strain DSM 14940 and *Aureobasidium pullulans* strain DSM 14941). Analysis for viability of the combined active ingredients and for quality measures over 30 months at 8 and 20°C showed Botector and Blossom Protect are considered stable formulations for up to 30 months at 8°C and for 18 months at 20°C.
CLASSIFICATION: ACCEPTABLE.

DATA EVALUATION RECORD

Primary review by: Joel V. Gagliardi, Ph.D.
Secondary review by: John L. Kough, Ph.D.

Study Types	Physical and Chemical Characteristics (830.6317).
MRID Nos.	503328-01; 503328-02.
Test Materials	Botector and Blossom Protect containing *Aureobasidium pullulans* strain DSM 14940 and *Aureobasidium pullulans* strain DSM 14941.
Study Nos.	L1310BP14-01B08; L1310BP14-01B20.
Sponsor	BIO-FERM GmbH; Technopark 1; A-3430 Tulln.
Testing Facility	Bio-Protect GmbH; Lohnerhofstr. 7; D-78467 Konstanz.
Titles of Reports	Storage stability of the formulation Blossom Protect™ over 30 months at 08°C; Storage stability of the formulation Blossom Protect™ over 18 months at 20°C.
Author	Dr. Stefan Kunz.
Studies Completed	April 10, 2016; September 10, 2015.
Study Summaries	The registrant submitted studies on only one of the end-use products with the rationale that Botector contains only active ingredients (50% by weight each of *Aureobasidium pullulans* strain DSM 14940 and *Aureobasidium pullulans* strain DSM 14941) and Blossom Protect is the same formulation with a single inert ingredient at 35.5% (32.25% by weight each of *Aureobasidium pullulans* strain DSM 14940 and *Aureobasidium pullulans* strain DSM 14941). Analysis for viability of the combined active ingredients and for quality measures over 30 months at 8 and 20°C showed Botector and Blossom Protect are considered stable formulations for up to 30 months at 8°C and for 18 months at 20°C.
Classifications	**ACCEPTABLE.**
Good Laboratory Practice	A signed and dated GLP statement was included. The studies were performed according to the requirements of 40 CFR Part 160 except there was no approved protocol per 160.120(a) or quality assurance unit per 160.185(14).

I. SUMMARY OF PHYSICAL AND CHEMICAL PROPERTIES: presented in Tables 1-2.

Table 1. Summary storage stability data for Blossom Protect at 8-20°C.

Temperature	8°C				20°C				Standard
Months	0	12	24	30	0	6	12	18	(minimum)
Viability (CFU/g)	$5.6x10^{9}$	$5.6x10^{9}$	$3.7x10^{9}$	$3.1x10^{9}$	$5.6x10^{9}$	$5.6x10^{9}$	$5.2x10^{9}$	$4.6x10^{9}$	$8.8x10^{8}$ CFU/g
Persistent foaming (mL)	2.5	0	0	0	2.5	0	0	0	
Wettability (99%)	49	42	50	47	49	46	45	29	
Dry Sieve (10-90%)	250-2000	75-2000	250-2000	250-2000	250-2000	125-2000	500-2000	75-2000	
Dispersibility (%)	77.5	87.4	80.2	88.7	77.5	83.1	59.9	82.4	
Suspensibility (%)	96.2	86.2	85.3	89.2	96.2	91.5	89.0	85.1	
Wet Sieve (% residue)	0.24	0.16	0.21	0.10	0.24	0.21	0.19	0.14	
pH	6.9	6.4	6.4	6.4	6.9	6.4	6.3	6.3	
Dustiness	10.2	9.8	6.3	9.8	10.2	5.7	8.7	23.0	
Friability (%)	99.4	99.6	99.7	99.6	99.4	99.8	99.6	99.7	

TABLE 2. Description of Chemical and Physical Properties for Blossom Protect at 8-20°C.

Guideline	Property	Result	Method/Reference
830.6317	Storage Stability	Stable at least 30 months at 8°C. Stable at least 18 months at 20°C.	Viable counts on Malt Extract Agar, 25°C, 72 hours.

DEFICIENCIES: None.